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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,112	09/27/2006	Murray Goodman	00015-038US1/SD2001-203-1	6290

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
07/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,112	GOODMAN ET AL.	
	Examiner	Art Unit	
	D L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2010 and 13 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *8-10 and 15-19* is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 11-14* is/are allowed.

6)☒ Claim(s) *2,3, and 5* is/are rejected.

7)☒ Claim(s) *4,6 and 7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 2/13/06 wherein claims 9, 13, and 15-17 were amended and claims 18 and 19 were added.

Note: Claims 1-19 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to compounds having SEQ ID Nos. 1-10 and those of independent claim 11. In addition, the invention discloses pharmaceutical compositions comprising the compounds and methods of using the compounds/compositions.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election of Group I (claims 1-7 and 11-14) in the reply filed on 5/28/10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Notes: Applicant's election of species, SEQ ID No. 1, is acknowledged in the response filed 5/28/10. Initially, Applicant's elected species was searched. However, since no prior art was found which could be used to reject the claims, the search was expanded over the full scope of Group I.

WITHDRAWN CLAIMS

4. Claims 8-10 and 15-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

112 FIRST PARAGRAPH REJECTIONS

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates the iodination of SEQ ID Nos. 1-10. Specifically, review of Applicant's disclosure (pages 8-9, paragraph [0029]) indicates that for the compounds having Formula I: C-c[Cys-Tyr-D-Trp-Lys-Val-Cys]-Y-NH_2 that it is the Tyr at the third position that is ***mono-*** or **polyiodinated**. However, claim 8 as written indicates that any position on the sequences may be ***di-*** or ***polyiodinated aromatic modification***. As a result, there is an inconsistency between

the actual disclosure and what appears in claim 8. Thus, based on claim 8 as written, what the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

112 SECOND PARAGRAPH REJECTIONS

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2, 3, and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2: The claim as written is ambiguous because of the phrase 'di- or polyiodinated aromatic modification'. In particular, it is unclear what particular iodinated aromatic modifications Applicant is claiming that are compatible with the instant invention.

Claims 3 and 5: First, the claims are ambiguous because it is unclear what analog(s) Applicant is/are referring to. Secondly, claims 3 and 5 recite the limitation "the analog" in lines 2 and 1, respectively. There is insufficient antecedent basis for this limitation in the claim.

ALLOWABLE CLAIMS

9. Claims 1 and 11-14 are allowable over the prior art of record.

CLAIM OBJECTIONS

10. Claims 4, 6, and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

PRIORITY DOCUMENT

11. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 8/22/03. It is noted, however, that applicant has not filed a certified copy of the 2003-208390 application as required by 35 U.S.C. 119(b).

COMMENTS/NOTES

12. It should be noted that no prior art has been cited against the instant invention. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious the compounds having SEQ ID Nos. 1-10, compounds of independent claim 11, or methods of uses thereof.

13. The Examiner respectfully requests that Applicant insert SEQ ID Nos. 1-10 (the actual sequences) into independent claim 1 for clarity of the claim.

14. It should be noted that the product claims have not been rejoined with the method claims. Applicant is reminded of the rejoinder paragraph (see below) which sets forth that withdrawn process claims must require the limitation of the allowable product claim(s). In addition, the paragraph discloses that the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 102, 103, and 112. As a result, Applicant is respectfully requested to reviews the withdrawn claims. Applicant may want to evaluate the claims to make sure the necessary conditions are met to result in the rejoining of the claims. Possible items to consider are as follows: (1) whether or not the claims disclose all of the necessary steps for visualizing the malignant cells (i.e., what happens after administering the compound to the subject, for example, see claim 8); (2) what proliferative disorder(s) may be treated with the instant invention (for example, see claim 9); (3) proper Markush format (for example, see claim 10); (4) what somatostatin receptor effect is elicited and if all

method steps are present. What happens after administering the compound to determine if a desired condition is met (for example, see claim 15); (5) proper Markush format and what happens after administering the compound to treat desired conditions (for example, see claims 16 and 18); and (6) whether or not the instant application actually inhibits (prevents) the proliferation of Helicobacter pylori or if the condition is treated instead. Also, what happens after administering the compounds to determine if the compound actually inhibited or treated the desired condition.

Rejoinder Paragraph

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
Art Unit 1618

July 1, 2010